REMARKS

In response to the Office Action mailed on May 27, 2005, Applicants submit this Amendment and a Request for Continued Examination (RCE) filed concurrently herewith.

As an initial matter, Applicants would like to thank Examiners Prone and McDermott for allowing and conducting the telephonic interview of July 20, 2005. The substantive matters discussed in the interview are incorporated in the remarks set forth below. Additionally, although Applicants agree with the identification of claims and prior art in the Examiner's Interview Summary paper of July 21, 2005, Applicants do not necessarily agree with at least certain characterizations and conclusions asserted by the Examiner.

Specifically, in the Interview Summary paper, the Examiner stated that

> [a]pplicants suggest amending claims 31 and 36 to recite that the second marker band is "at" the proximal end of the self-expanding stent. The examiners believed that this amendment might make the [claims] allowable over the current rejection but believe that other art is available that [the claims] will not overcome. The applicants also recognized that the current rejection over claim 1 is according to a broad interpretation, but that it does reject the claim in its current condition.

Applicants agree that amending claims 31 and 36 to recite "that the second marker band is 'at' the proximal end of the self expanding stent" was suggested to the Examiners. Additionally, Applicants agree that the Examiners "believed that this amendment might make the claim allowable over the current rejection." The Examiners suspected that an additional search of the art may reveal other pertinent prior art.

Regarding the characterizations and conclusions asserted with respect to claim 1, Applicants respectfully disagree with the Examiners' account of the substance of the interview. Rather, during the interview, Applicants argued that the claim rejections under 35 U.S.C. § 103(a) over Ravenscroft (U.S. Patent No. 5,702,418) in view of Fischell et al. (U.S. Patent No. 5,743,874) were improper because the Examiner failed to provide proper reasons or motivation for combining these references.

In particular, Applicants argued that the asserted motivation and rationale for modifying Ravenscroft with Fischell et al. was improper. Additionally, Applicants disagreed with the Examiner's interpretation of Applicants' Remarks filed on February 23, 2005. See May 27, 2005, Office Action at page 6. Rather than admitting that "the need for a step for visualizing a position corresponding to a distal most end of the stent prior to deploying the stent is eliminated [through the] combination," Applicants explained that the Remarks filed on February 23, 2005, stated that the alleged combination would, in at least some circumstances, result in an additional procedure being used during stent deployment.

In response to Applicants' arguments, Supervisory Patent Examiner McDermott conceded that the instant claim rejections over Ravenscroft in view of Fischell et al. appeared to lack proper reasons or motivation for combining these references. Examiner McDermott, however, suspected that a further search of the art may reveal other pertinent prior art.

Should the Examiner disagree with Applicants' comments on the substance of the interview, the Examiner is invited to contact the undersigned in order to resolve such disagreement.

In the Office Action of May 27, 2005, the Examiner rejected claims 1-4, 7-13, 15, 16, 29, 30, 32-35, and 44 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ravenscroft (U.S. Patent No. 5,702,418) in view of Fischell et al. (U.S. Patent No. 5,743,874); rejected claims 5-6 and 17-28 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ravenscroft in view of Fischell et al. and further in view of Lenker et al. (U.S. Patent No. 5,749,921); and rejected claims 31 and 36-43 under 35 U.S.C. § 103(a) as allegedly being unpatentable over St. Germain et al. (U.S. Patent No. 5,534,007) in view of Fischell et al. and further in view of Lenker et al. The Examiner made the rejections final.

By this Amendment, Applicants amend the specification to correct a minor typographical error, amend claims 1, 5, 17, 18, 19, 29, 31, 36, and 44, and cancel claims 14, 22, 35, and 42. Accordingly, claims 1-13, 15-21, 23-34, 36-41, and 43-44 remain pending in this application. Of these claims, claims 1, 5, 17, 29, 31, 36, and 44 are independent.

Applicants respectfully traverse the Examiner's rejection of claims 1-4, 7-13, 15, 16, 29, 30, 32-35, and 44 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Ravenscroft in view of Fischell et al. Neither reference, taken alone or in combination, teaches or suggests each and every element of independent claims 1, 29, and 44. In particular, the applied references at least fail to disclose the claimed combination including a catheter having a distal end, a holding sleeve configured to retain a stent, and an inflatable device, wherein the inflatable device is disposed solely between the holding sleeve and the distal end of the catheter, and wherein at least a

portion of the stent overlaps a portion of the inflatable device prior to deployment of the stent.

Ravenscroft discloses a stent delivery system 10 having, among other things, an elongated catheter 11, an axially extending plastic core 14 having a flexible thin portion 17, and first and second rings 23 attached to the thin portion 17. Ravenscroft further discloses that a balloon 60 may underlie a stent 50 to aid in stent expansion. See col. 7, lines 10-18; and Fig. 7 of Ravenscroft.

Ravenscroft, however, does not disclose or suggest that the balloon "is disposed solely between [a] holding sleeve and the distal end of the catheter." Even assuming that the first and second rings 23, collectively or alone, can be construed to read on the recited "holding sleeve," which Applicants do not necessarily concede, balloon 60 is not disposed solely between the holding sleeve and the distal end of the catheter. See Fig. 7 of Ravenscroft. Accordingly, Ravenscroft fails to teach each and every element of amended independent claims 1, 29, and 44.

Fischell et al. teaches an integrated catheter that may be used for both balloon angioplasty and stent deployment, but fails to teach the claimed combination including a catheter having a distal end, a holding sleeve positioned about a tubular member and configured to retain a stent, and an inflatable device positioned about the tubular member, wherein the inflatable device is disposed solely between the holding sleeve and the distal end of the catheter, and wherein at least a portion of the stent overlaps a portion of the inflatable device prior to deployment of the stent. Moreover, the Examiner has relied on Fischell et al. solely for the alleged teaching of "an integrated catheter delivery device comprising fluid ports 33, 29, 44, a holding sleeve 20, and a first marker

band 80 or 180." Thus, Fischell et al. fails to overcome the above described deficiencies of Ravenscroft, and claims 1, 29, and 44, and their dependent claims, are allowable over the Examiner's proposed combination of these references.

In addition, and as a second and independent basis for traversing the Examiner's rejections of claims 1, 29, and 44 over Ravenscroft in view of Fischell et al., the asserted motivation and rationale for combining these references is improper.

As discussed in the above-mentioned interview, nothing suggests that the procedures for deploying the stent by the Ravenscroft device will be reduced by including a marker band at a distalmost end of the stent. Indeed, in at least some instances, an additional procedure may be used during stent deployment, i.e., visualizing a position corresponding to a distalmost end of the stent prior to deploying the stent. The proposed modification also will not result in the use of less devices, or any less device exchange, to deploy the stent with the Ravenscroft device. The mere assertion that Ravenscroft may be modified by Fischell et al. does not render the combination obvious unless these references suggest the desirability of the combination. The references do not, and the rejection does not provide proper reasons or motivation for the combination. For these reasons, the rejection does not establish a *prima facie* case of obviousness, and independent claims 1, 29, and 44, and their dependent claims, are allowable over the applied references.

Applicants respectfully traverse the rejections of claims 5, 6, and 17-28 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Ravenscroft in view of Fischell et al. and further in view of Lenker et al. Even if Lenker et al. teaches what the Examiner alleges (and Applicants do not necessarily agree that it does), this reference fails to

overcome the shortcomings of the references discussed above. Accordingly, claims 5, 6, and 17-28 are allowable at least for the reasons discussed above with respect to Ravenscroft and Fischell et al.

Applicants respectfully traverse the rejections of claims 31 and 36-43 under 35 U.S.C. § 103(a) as being allegedly unpatentable over St. Germain et al. in view of Fischell et al. and further in view of Lenker et al. None of these references, taken alone or in combination, teaches or suggests each and every element of independent claims 31 and 36. In particular, the applied references at least fail to disclose the claimed combination including a catheter having a distal end, a holding sleeve configured to retain a stent around the holding sleeve, and an inflatable device, wherein the inflatable device is disposed solely between the holding sleeve and the distal end of the catheter.

St. Germain et al. discloses a stent delivery system having, among other things, a catheter 5, a retractable distal sheath 40, and a stent 35. St. Germain et al. further discloses that a balloon expandable stent could also be utilized by arranging the stent around an optional placement balloon, which is not shown in the figures.

St. Germain et al., however, does not disclose or suggest a catheter having a distal end, a holding sleeve configured to retain a stent around the holding sleeve, and an inflatable device, wherein the inflatable device is disposed solely between the holding sleeve and the distal end of the catheter. Accordingly, St. Germain et al. fails to teach each and every element of amended independent claims 31 and 36.

The Examiner has relied on the teachings of Fischell et al. and Lenker et al. to cure the deficiencies of the St. Germain et al. reference. However, even if Fischell et al. and Lenker et al. teach what the Examiner alleges (and Applicants do not necessarily

agree that they do), these references fail to overcome the shortcomings of the St. Germain et al. reference discussed above. Accordingly, independent claims 31 and 36, and their dependent claims, are allowable over the applied references.

In addition, as a second and independent basis for traversing the Examiner's rejection of claims 31 and 36-43 over St. Germain et al. in view of Fischell et al. and further in view of Lenker et al., the applied references, taken alone or in combination, fail to teach the required number and positioning of the marker bands recited in claims 31 and 36. In particular, claims 31 and 36 each recites, among other things, a catheter including a first marker band at a position corresponding to a distalmost leading end of a self-expanding stent, a second marker band at a position corresponding to a trailing end of the self-expanding stent, and a third marker band between the first and second marker bands.

St. Germain et al., the primary reference, does not disclose marker bands, and the Office Action does not assert otherwise. In its embodiments, the Fischell et al. reference discloses two markers (for example, see 80 and 82 in Fig. 1, and 180 and 182 in Fig. 4). Fischell et al., however, does not disclose a third marker. The Lenker et al. reference does not cure the deficiencies of either St. Germain et al. or Fischell et al. Independent claims 31 and 36, and dependent claims 37-43, are therefore allowable over the applied references.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

In discussing the specification, claims, and drawings in this Amendment, it is to be understood that Applicants are in no way intending to limit the scope of the claims to an exemplary embodiment described in the specification or abstract and/or shown in the drawings. Rather, Applicants are entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

In view of the foregoing remarks, Applicants respectfully request reconsideration and re-examination of this application and the timely allowance of the pending claims. If the Examiner would like to discuss this case, he is invited to contact the undersigned at 202-408-4140.

Please grant any extensions of time required to enter this Amendment and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: September 19, 2005

By: _____
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